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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,403	12/10/2001	Leslie A. Holladay	011293-9028	4840
23510	7590	09/27/2004	EXAMINER	
MICHAEL BEST & FRIEDRICH, LLP ONE SOUTH PINCKNEY STREET P O BOX 1806 MADISON, WI 53701			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,403	Applicant(s) HOLLADAY, LESLIE A.	
	Examiner David J Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-27 is/are pending in the application.
- 4a) Of the above claim(s) 5-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4 and 17-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1]** Claims 1-2 and 4-27 are pending in the application.
- [2]** Applicants' election with traverse of Group III, claims 1-2, 4, and 25-27, drawn to a method for delivering a pharmaceutical polypeptide agent by providing a synthetic analog of human growth releasing hormone, is acknowledged.
- [3]** In view of applicants' argument that claims 17-18 should be included in all of Groups I-III and in view of applicants' request that claim 1 be regarded as a linking claim, the instant Office action is a supplemental restriction requirement indicating that claim 1 is a linking claim, per applicants' request.
- [4]** In view of the instant supplemental restriction requirement, the examiner will respond to applicants' arguments in response to the restriction mailed December 24, 2003 in a subsequent Office action.
- [5]** Claims 5-16 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As such, claims 5-16 have not been included below.
- [6]** In a telephone conversation with Ms. Sally Sorensen on September 01, 2004, it was noted by Ms. Sorensen that page 4 of the response filed March 29, 2004, which includes the signature of the attorney of record, was inadvertently omitted. The examiner suggested that Ms. Sorensen FAX all pages of the response filed March 29, 2003 including omitted page 4 such that the response could be scanned and filed in the application.

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[7] It is noted that the examiner failed to provisionally reject claims 1-2, 4, and 17-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 17-18 of co-pending US non-provisional application 08/466,610 in the first Office action on the merits mailed March 06, 2003. As this provisional rejection will not be necessitated by amendment, the Office action, in response to applicants' election as set forth below, will be non-final. However, in the interest of compact prosecution, it is noted that applicant may file a terminal disclaimer in compliance with 37 CFR 1.321(c) to avoid a provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Applicants are advised that, if a terminal disclaimer is submitted, the Office action in response to applicants' election as set forth below may be made final.

Election/Restrictions

[8] Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim(s) 2, 4, and 17-21, drawn to a method for delivering a pharmaceutical polypeptide agent, by providing a synthetic analog of human granulocyte colony stimulating factor, classified in class 514, subclass 2.
- II. Claim(s) 2, 4, 17-18, and 22-24, drawn to a method for delivering a pharmaceutical polypeptide agent, by providing a synthetic analog of human parathyroid hormone, classified in class 514, subclass 2.

- III. Claim(s) 2, 4, 17-18, and 25-27, drawn to a method for delivering a pharmaceutical polypeptide agent, by providing a synthetic analog of human growth releasing hormone, classified in class 514, subclass 2.

[9] The inventions are distinct, each from the other because:

[10] The methods of Groups I-III are independent as they utilize different products, *i.e.*, structurally and functionally distinct polypeptides.

[11] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-III are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. In this case, as each group recites a different polypeptide, each having a distinct structure and function, thus a separate patent and non-patent literature and sequence search is required for each Group. Thus, co-examination of the inventions of Groups I-III would place a serious burden on the examiner.

[12] Claim 1 link(s) inventions I, II, and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the

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instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

[13] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[14] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.


David J. Steadman, Ph.D.

Primary Examiner

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09-23-04